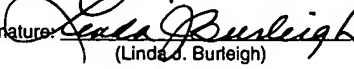


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(Linda J. Burleigh)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION FOR U.S. LETTERS PATENT

Title:

MULTIFUNCTION ADAPTOR FOR AN OPEN-ENDED CATHETER

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MULTIFUNCTION ADAPTOR FOR AN OPEN-ENDED CATHETER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] Not applicable.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] Not applicable.

REFERENCE TO A COMPACT DISK APPENDIX

[0003] Not applicable.

FIELD OF INVENTION

[0004] The present invention is generally in the field of medical devices. More particularly, the present invention relates to a multifunction adaptor for an open-ended catheter.

BACKGROUND OF THE INVENTION

[0005] There are a variety of conditions that require injection of fluids into, or withdrawing fluids from, parts of a body below the surface of the skin of the body. During the procedure, symptomatic gas embolism can occur when undissolved gas (*e.g.*, air, CO₂) accumulates in the heart and/or pulmonary arteries. This gas can compromise the circulation of blood through the lungs, causing serious injury or death.

[0006] *Health Devices* May-Jun 1996; 25(5-6):214-5 reported a case of suspected gas embolism. During a hysteroscopy (performed with a patient under intravenous sedation), the patient gasped for air almost immediately upon uterine insufflation. Based on the clinical signs, the medical staff suspected that the patient's condition was caused by a CO₂ embolism that originated in the uterus. However, a follow up investigation revealed that the embolized gas was probably air, not CO₂. The air may have been introduced into the patient from the dead space in the tubing set used to connect the insufflator to the hysteroscope. This tubing set was not purged before insufflation began. *Health Devices* recommended that before delivering a fluid to a

patient, one must purge air from tubing sets and instruments. Thus, there is a need for a multifunction adaptor for use with an open-ended catheter wherein the multifunction adaptor can be connected to a syringe to infuse the catheter with saline or purge air from the catheter.

[0007] A subcutaneously tunneled catheter is often selected when a catheter might be required to be implanted within a patient for weeks to months. A subcutaneously tunneled catheter can be implanted or removed in the outpatient setting and has a decreased incidence of infection. The typical procedure for implanting the tunneled catheter is by forward tunneling. However, a more preferred method of implanting the tunneled catheter is by reverse tunneling as follows: (a) place the distal end of the catheter within the blood vessel through an entry site; (b) mark an exit locations of a tunnel to be formed in a subcutaneous plane; (c) create the subcutaneous tunnel from the exit to entry site using a tunneler by pushing the sharp point of the tunneler through the skin; (d) attach the proximal end of the catheter to the sharp point of the tunneler; (e) pull the tunneler with the secured catheter from the entry to the exit site, through the subcutaneous tunnel, while gently holding the catheter distal to the cuff ; and (f) detach the catheter from the tunneler and attach a bifurcation element thereto. During the described reverse tunneling technique, the proximal end of a typical catheter tube is open, permitting the entry of air. If the proximal end is clamped, the catheter cannot be reverse tunneled as described. Therefore, there is a need for a multifunction adaptor wherein one end could be attached to the tunneler tip and other end could be attached to the proximal end of an open end of the catheter.

[0008] It is common to use an implanted catheter to repeatedly access the vascular system of a patient. A flexible guidewire placed in the vascular system can be used to facilitate placement of the catheter, but its use can prevent capping the catheter to prevent fluid loss from or air entering the vascular system during placement. After catheter placement, it is common to attach a valved cap to the catheter connector(s) to prevent fluid loss from or air entering the catheter and vascular system.

[0009] U.S. Pat. No. 6,575,960 (Bleed Back Control Assembly and Method) relates to a Y-valved connector. The 'Y-connector' includes a sealing valve that is normally closed except when accessed with a small diameter tube or wire. The sealing valve does not completely prevent air or fluid leakage, but relies on a second user compressible valve to provide a complete seal.

[0010] In short, there are several problems with the current valves. The flow path through the valve is restricted due to a restricted cross-sectional area. There is a dead space above or below the valve where blood accumulates, which makes it difficult to clean the valve. The current valves are not designed for use with a guidewire traversing through the same valve. Also, the valves cannot be accessed multiple times; they are typically screwed on to the catheter and discarded after use.

[0011] Therefore, there is a need for a multifunction adaptor that solves the above-mentioned problems and thereby reduces the risk of contamination and permits repeated use of the multifunction adaptor.

SUMMARY OF THE INVENTION

[0012] The multifunction adaptor of this invention includes a valved tubing, *i.e.*, a tubing that itself has been shaped to create a valve. The multifunction adaptor is for use with an open-ended catheter such that the multifunction adaptor provides multiple functions, such as, for example: (a) sealing the catheter tube except when being accessed by a syringe or a guidewire to prevent blood loss or air embolism, (b) attaching to a standard luer fitting such as that of syringe to allow flushing of the catheter with a fluid such as saline, (c) operating as a tunneler connector, and (d) providing for an “over the guidewire” placement or replacement technique. In addition, it should be appreciated that other advantageous functions would be provided by the multifunction adaptor of the present invention.

[0013] In one embodiment of the present invention, a slit valve hub connector comprises a hub connector and a slit valve, wherein the hub connector is capable of being attached to a catheter tube and the slit valve seals the catheter tube except when being accessed by an introducer to prevent blood loss or air embolism.

[0014] In another embodiment of the present invention, a catheter valve hub connector comprises a hub connector and a catheter tube having a slit valve built-in as an integral part of the catheter tube, wherein the slit valve seals the catheter tube except when being accessed by an introducer to prevent blood loss or air embolism.

[0015] In yet another embodiment of the present invention, a valve tubing hub connector comprises a hub connector and a tubing having a slit valve built-in the tubing, wherein the hub connector is capable of being attached to a catheter tube and the slit valve seals the catheter tube except when being accessed by an introducer to prevent blood loss or air embolism.

[0016] These and other embodiments, features and advantages of the present invention will become more apparent to those skilled in the art when taken with reference to the following more detailed description of the invention in conjunction with the accompanying drawings that are first briefly described.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] In the accompanying drawings, reference characters refer to the same parts throughout the different views. The drawings are intended for illustrating some of the principles of providing a multifunction adaptor and are not intended to limit the description in any way. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the depicted principles in a clear manner.

[0018] FIG. 1 is a cross-sectional view of a slit valve hub connector according to the present invention attached to a proximal end of a catheter.

[0019] FIG. 2 is a partial cross-sectional view of a syringe connected to the slit valve hub connector of FIG. 1.

[0020] FIG. 3 is a cross-sectional view of a tunneler connected to the slit valve hub connector of FIG. 1.

[0021] FIG. 4A is a cross-sectional view of another embodiment of a slit valve hub connector according to the present invention.

[0022] FIG. 4B is a cross-sectional view of yet another embodiment of a slit valve hub connector according to the present invention.

[0023] FIG. 4C is a cross-sectional view of the slit valve hub connector with a guidewire passing therethrough.

[0024] FIG. 4D is a cross-sectional view of a syringe connected to a slit valve hub connector according to the present invention.

[0025] FIG. 4E is a cross-sectional view of a tunneler connected to a slit valve hub connector according to the present invention.

[0026] FIG. 5A is a cross-sectional view of a proximal end of a catheter having a valve formed therein.

[0027] FIG. 5B is a cross-sectional view of the catheter of FIG. 5A with a hub connector overmolded thereon.

[0028] FIG. 5C is a cross-sectional view of the catheter valve hub connector of FIG. 5B with a guidewire passed therethrough.

[0029] FIG. 5D is a cross-sectional view of a syringe connected to the catheter valve hub connector of FIG. 5B.

[0030] FIG. 5E is a cross-sectional view of a tunneler connected to the catheter valve hub connector of FIG. 5B.

[0031] FIG. 6A is a cross-sectional view of a preformed valve tube according to the present invention.

[0032] FIG. 6B is a cross-sectional view of a hub connector according to the present invention.

[0033] FIG. 6C is a valve tubing hub connector according to the present invention attached to a catheter.

[0034] FIG. 7A is a cross-sectional view of another embodiment of the multifunction adaptor according to the present invention.

[0035] FIG. 7B is a cross-sectional view of a syringe attached to the multifunction adaptor of FIG. 7A.

[0036] FIG. 7C is a cross-sectional view of a tunneler attached to the multifunction adaptor of FIG. 7A.

DETAILED DESCRIPTION OF THE INVENTION

[0037] The detailed description illustrates by way of example, not by way of limitation, the principles of the invention. This description will clearly enable one skilled in the art to make and use the invention, and describes several embodiments, adaptations, variations, alternatives and uses of the invention, including what is presently believed to be the best mode of carrying out the invention.

[0038] The multifunction adaptor may be used for facilitating the introduction or removal of fluid to or from a body. The multifunction adaptor may be temporarily attached to a luer fitting connector of a catheter or it may be permanently attached to the catheter in lieu of the luer fitting connection. The multifunction adaptor could be coupled to a catheter, which may be utilized for chronic excess fluid drainage from a body. In other applications, the multifunction adaptor could be coupled to an implantable electromechanically powered and/or magnetically coupled vesicular pump to permit assisted flow of a fluid into or out of a body. This flow may be uni-directional.

[0039] A multifunction adaptor is attached to the open (proximal) end of an attachable catheter tube (single or multi-lumen, silicone or polyurethane). The valve of the multifunction adaptor seals the catheter tube except when being accessed by a syringe (for infusion or aspiration) or a guidewire. One of the purposes of the valve is to seal off the open end of the catheter during placement into the vein. This prevents blood loss or air embolism that may occur if the catheter end is open, as in the case for attachable catheters. A second design feature utilizes the multifunction adaptor to be attached to a standard luer fitting (*i.e.*, syringe). With a syringe attached to the multifunction adaptor, the catheter may be infused (flushed with saline) or aspirated to verify blood flow through the catheter. By utilizing the multifunction adaptor, adapters and clamps are unnecessary. A third design feature allows passage of the catheter/multifunction adaptor assembly over a guidewire. The guidewire can be inserted into the catheter tip (distal end) and passed through the guidewire guide in the valve of the multifunction adaptor to guide the guidewire through the valve slit of the valve and through the multifunction

adaptor assembly. Passing the guidewire through the valve minimizes risks associated with blood loss and/or air embolisms possible in an open end catheter design. A fourth design feature allows attachment of the multifunction adaptor to a subcutaneous tunneler without any additional attachments or adapters.

[0040] The multifunction adaptors of this invention are broadly classified as: (1) a slit valve hub connector; (2) a catheter valve hub connector; and (3) a valved tubing hub connector. FIG. 1 shows a schematic of a slit valve hub connector according to the present invention. Valved hub connector 100 is preferably made of hard material that has rigidity like that of rigid polyurethane and has first and second ends. The valved hub connector 100 is attached at a distal end thereof to an open proximal end of a catheter tube 20, which can be in single or multiple lumen configurations and which are generally made of a polymer material, including silicone and polyurethane. The slit valve hub connector 100 could be attached to the catheter by solvent bonding or by any other method of bonding or overmolding.

[0041] The valve 102 is preferably made of silicone and seals the catheter tube except when being accessed by a syringe (for infusion or aspiration) or a guidewire. The valve 102 provides for an “over the guidewire” placement or replacement technique with no blood loss or air embolism. A guidewire can be inserted into the distal end of the catheter and passed through a guidewire guide 104 in the valve hub connector 100 to guide the guidewire through the slit 106 of the valve 102 and through the hub connector 100. In one embodiment, the second end of the slit valve hub connector 100 that is not attached to the open end of the attachable catheter tube may contain a luer taper 108 as shown in FIG. 1. The design of the slit opening could be a single layer slit, a two layer slit or a triple layer design with a slit followed by a hole opening, followed by another slit opening. The hub connector 100 will generally be made of a harder material than will the valve 102. For example, the hub connector 100 may have a hardness in the range of approximately 90 Shore A to 90 Shore D, while the valve 102 may have a hardness in the range of approximately 40 Shore A to 60 Shore A. However, in one embodiment, the hub connector has a hardness in the range of approximately 70 Shore A to 80 Shore A.

[0042] In valved connector 100, the proximal end thereof not attached or connected to the proximal end of an attachable catheter tube could have luer taper 108 and snap-on piece,

such as an O-ring 110, to allow attachment with a standard luer such as a syringe, as shown in FIG. 2, and for attachment of the tip 52 of a tunneler 50 as shown in FIG. 3. While the luer taper and snap-on piece may be preferable for attachment to certain medical instruments, it should be noted that valved connector 100 would be suitable for attachment to, or use with, many different types of medical instruments, including guidewires, syringes and tunnelers, with or without said features.

[0043] One variation of the multifunction adaptor of the present invention is a slit valve hub connector 200 with a built-in slit valve 206 as shown in FIG. 4B. The valved hub connector 200 is preferably made of soft material that it has rigidity like that of soft polyurethane (*e.g.*, in the range of approximately 60 Shore A to 90 Shore A.) Of course, the hub connector 200 could be made of a harder material, such as in the range of approximately 80 Shore A to 70 Shore D. There are many ways to manufacture the built-in slit valve 206. For example, as shown in FIG. 4A, one method would be to mold the hub connector 200, comprised of a soft material, with a necked portion 202 such that there is initially no opening between the first and second ends as indicated by the solid area 204 therebetween. A slit could then subsequently be formed through the necked portion to form slit valve 206 as shown in FIG. 4B. An alternative method would be to initially create the necked portion 202 with an opening therethrough as shown in FIG. 4B.

[0044] As discussed above, the multifunction adaptor of the present invention can be used to connect to medical instruments to facilitate the use thereof with a catheter. As shown in FIGS. 4C-4E, the valve hub connector 200 can be utilized to allow safe passage of a guidewire 30 through a placed catheter 20 without risk of blood loss or air embolism (FIG. 4C), to connect catheter 20 to a flushing syringe (FIG. 4D) and to connect catheter 20 to a tunneler 50 (FIG. 4E). Of course, the multifunction adaptor of the present invention could be used in conjunction with many other medical instruments as well.

[0045] FIGS. 5A-5B illustrate another embodiment of the multifunction adaptor of the present invention, catheter valve hub connector 300. In this embodiment, a thermoplastic catheter tube 22 is thermoformed to create a valve 302 as shown in FIG. 5A. Over-molded over the valve 302 on the proximal end of the tube 22 is a housing 304, resulting in the hub connector 300. It should be noted that although the catheter tube 22 is shown in a dual-lumen configuration,

the valve hub connector 300 would equally be applicable to a single or multi-lumen design. The valve 302 seals the catheter tube lumen(s) except when being accessed by a syringe or a guidewire as shown in FIGS. 5C-5D. One of the purposes of the valve 302 is to seal off the open end of the catheter during placement into a blood vessel. The valve 302 prevents blood loss or air embolism that may occur in an open ended catheter. As with the embodiments described above, the catheter hub connector 300 permits attachment of a syringe 40 thereto such that the catheter 22 may be infused (*e.g.*, flushed with saline), as shown in FIG. 5D. By utilizing the valved hub connector, adapters and clamps are unnecessary. As shown in FIG. 5E, the catheter hub connector 300 also permits attachment to a subcutaneous tunneler 50 without any additional attachments or adapters.

[0046] FIG. 6C shows yet another embodiment of the multifunction adaptor of the present invention, valved tubing hub connector 400. The hub connector 400 is manufactured by molding a housing 404 (FIG. 6B) over a preformed valve tube 402 (FIG. 6A). The housing 404 preferably made of hard material (*e.g.*, high durometer silicone), while the valve tube 402 is preferably made of a soft (*e.g.*, thermoplastic) material. Examples of the hardness of materials used for the housing 404 is in the range of approximately 60 to 90 Shore A, while examples for the hardness of the material used for the valve tube 402 is in the range of approximately 40 Shore A to 60 Shore A. The neck portion 406 of the hub connector 400 forms a seal to prevent passage of blood or air therethrough as with the above-described embodiments. The formed hub connector 400 is then attached to catheter 20. Alternatively, the valve tube 402 is first formed and placed into a mold adjacent the catheter 20 for over-molding the housing 404. As with the embodiments described above, hub connector 400 is used in like manner with medical instruments such as guidewires, syringes and tunnelers.

[0047] In another embodiment of the multifunction adaptor of the present invention, a tapered connector housing and removable syringe adaptor assembly 500, which allows a reverse tunneled catheter to be flushed and attached to the tip of a tunneler 50, is illustrated in FIG. 7A. It should be appreciated that the tapered connector housing and removable syringe adaptor could be design features for any of the embodiments described herein. The adaptor assembly 500 includes a tapered connector housing 502 and a removable syringe adaptor 504. As shown in FIG. 7B, a syringe 40 is attached to the syringe adaptor 504 for flushing a catheter attached to the

distal end of the connector housing 502. After flushing, the syringe adaptor is detached and discarded from the connector housing/catheter assembly. After the catheter is placed and the tunneler is positioned in the subcutaneous tunnel, the proximal end of the connector housing 502 is slid over the tip of the tunneler 50. A compression ring, such as O-ring 110 (FIG. 3), grips the tunneler tip, allowing the catheter to be withdrawn through the subcutaneous tunnel by pulling the connector 502 through to an exit site. The connector housing outside diameter creates the desired subcutaneous tunnel diameter while the tapered tip 506 eases the connector/catheter passage. The design allows use of a standard tunneler, a tunneler with a locking notch, or a tunneler with shallow threads at the tip to allow the tunneler to be removed (unthreaded) from the connector housing.

[0048] The multifunction adapter of the present invention may be designed to be small enough to fit within a cylindrical housing with maximum dimensions of 0.5" diameter and 1.0" length. The multifunction adapter may also be designed to be incorporated within a small housing that is compatible with multiple fittings, *i.e.*, luer lock, slip fit, compression, etc. Valve function or performance is not affected by the addition of color or clear housing/components. Component or housing components are not affected by opacity or color. Markings and scales could be used on an as needed basis per application. Device function is not integrally linked to markings, etc. The multifunction adapter of the present invention is sterilizable using standard techniques (EtO, gamma, etc.). The methods of manufacturing the multifunction adapter of the different embodiments include machining or molding the components of the valved tubing and hub connector. While the device is primarily contemplated for use in human patients, the invention will also have veterinary uses or product development purposes in equine, bovine, canine, feline, and other mammalian species.

[0049] The present invention has been described above in terms of certain preferred embodiments so that an understanding of the present invention can be conveyed. However, there are many alternative arrangements not specifically described herein, but with which the present invention is applicable. Although specific features have been provided, the present invention would equally be embodied by other configurations not specifically recited herein. The scope of the present invention should therefore not be limited by the embodiments illustrated, but rather it should be understood that the present invention has wide applicability with respect to connector

systems generally. All modifications, variations, or equivalent elements and implementations that are within the scope of the appended claims should therefore be considered within the scope of the invention.